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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,900	01/09/2002	William H. Harris	37697-0039	8865

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,900

Applicant(s)

HARRIS ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 37-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 37-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Claim Objections

Claims 42, 65-78, 82-84, 89, 90, 92, 93, and 95 are objected to because of the following informalities:

In claims 1, 37-80, 82-84, and 89-95, the parent application PCT/US99/16070 does support the subject matter claimed herein to a three-cup prosthesis of a shell, acetabular cup, and a femur cup. It appears that the Applicant is trying to claim the features of two embodiments as if they are of the same embodiment (Figure 1's embodiment combined with Figure 8's embodiment). There is no suggestion from the specification that this can be done. It also suggests that the present application is a continuation-in-part of the parent application PCT/US99/16070. For this reason, these claims lack proper antecedent basis from the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter of claims 42, 65-78, 89, 90, 92, 93, and 95. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The parent application PCT/US99/16070 does not support the subject matter claimed herein to a three-cup prosthesis of a shell, acetabular cup, and a femur cup. For this reason, these claims lack proper antecedent basis from the specification.

With regard to claims 1, 37-72, 79, 80, 82-84, and 89-95, the open ended ranges claimed appear to have original support, however, they appear to render the claim language indefinite because there is no definite upper limit; see MPEP 2173.05(c)(II) which is incorporated herein by reference.

Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 81-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 81-88, the claimed dimensions are based upon the pelvic socket size of an indefinite open-ended range. For this reason, the claimed dimensions cannot reasonably be ascertained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37, 38, 41, 42, 90 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham et al (US 5,549,700) in view of McKellop et al (US 6,165,220) and Townley (US 6,096,084). Graham discloses shell (13) which corresponds to the acetabular cup as claimed and cup(s) (18) and/or (20) which can be 2.0 or 3.5 mm thick which correspond to the femur cup as claimed; see Figure 3 and column 8, lines 12-36. However, Graham fails to disclose a "crosslinked" UHMWPE cup material as claimed or the head diameter of greater than 35 mm as claimed. McKellop, however, teaches that it was known to crosslink similar prosthetic cups in

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order to improve wear resistance; see the front page thereof as well as column 2, lines 12-18. Townley teaches that it was known to make femur heads in the size range of 38 to 55 mm; see column 7, lines 32-42. Hence, it is the Examiner's position that it would have been obvious to crosslink the internal surface of the Graham UHMWPE cup in order to improve wear resistance. Furthermore, it would have been obvious to make the cup(s) 18 and/or 20 capable of receiving heads of 35 mm or greater so that the larger size femur head implants or natural femurs of larger individuals could be used with Graham.

With regard to claim 42, the acetabular cup as claimed is met by cup (18) of Graham, and the femur cup as claimed is met by combination of all segments of (20) of Graham.

Claims 1, 37-41, 43-59, 61-62, 64-89, 91, 92, 94, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townley et al (US 6,096,084) in view of McKellop et al (US 6,165,220).

Townley meets the claim language where the acetabular cup as claimed is met by the porous cobalt chromium layer and/or the cement layer (301) of Townley, and the femur cup as claimed is met by the cup (300) of Townley. The cup thickness is obviously greater than 1 mm by inspection of the drawings and comparing the thickness of the cup the diameter of the ball; see Figures 1-8 and 8 as well as column 4, line 24 to column 6, line 35 and column 7, lines 54-58. However, Townley fails to disclose a "crosslinked" UHMWPE cup material as claimed. McKellop, however, teaches that it was known to crosslink similar prosthetic cups in order to improve wear resistance; see

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the front page thereof as well as column 2, lines 12-18. Hence, it is the Examiner's position that it would have been obvious to crosslink the internal surface of the Townley UHMWPE cup in order to improve wear resistance.

With regard to claims 41 and 42, the shell as claimed is met by the porous cobalt-chrome layer.

With regard to claims 40, 47, and 69, Townley discloses in Figure 8 a cup having a thickness about $3\text{mm}/22\text{mm}=0.14$ or 14% of the thickness of the head. Since the head can vary from 38 mm to 55 mm, the shell thickness can vary from about 5.3 mm to about 7.7 mm. Therefore, Townley fails to disclose a shell thickness of more than about 7.7 mm. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to increase the cup thickness because Applicants have not disclosed that the cup thickness provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because UHMWPE is sufficiently strong for its intended purpose at a thickness of 5 mm. Therefore, it would have been an obvious matter of design choice to modify Townley to obtain the invention as specified in the claims.

With regard to claims 50, 75, and 79, Townley discloses a ball having a diameter between 38 mm and 55 mm. Therefore, Townley fails to disclose the ball diameters claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to increase the ball diameter because Applicants have not disclosed that the 70 mm to 90 mm diameter ball

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provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because it would fit larger patients and give a larger wear area therefor. Therefore, it would have been an obvious matter of design choice to modify Townley to obtain the invention as specified in the claims.

With regard to claims 54, 55, 70, 71, the Examiner asserts that these claimed parameters are inherently present in the material disclosed by Townley as modified by McKellop because it is the same crosslinked material claimed and disclosed.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Townley and McKellop as applied to claim 1 above, and further in view of DeCarlo, Jr. (US 4,524,467). Townley fails to disclose the varying degrees of movement as claimed. However, DeCarlo discloses that greater degrees of freedom with partial hemispheric portions were known to the art; see the abstract and figures. Hence, it is the Examiner's position that it would have been obvious to put partial hemispheric portions in the Townley device for the same reasons that DeCarlo does the same.

Claims 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townley and McKellop as applied to claim 1 above, and further in view of Teinturier (US 4,385,405). Townley fails to disclose an ovoid head as claimed. However, Teinturier teaches that it was known to make contact surfaces for ovoid heads; see column 4, lines 18-26. Therefore, it would have been obvious to make ovoid heads in the Townley device in order to correspond to the shape of the cup of Teinturier.

Response to Arguments

Applicant's arguments filed December 24, 2003 have been fully considered but they are not persuasive or were rendered moot.

In response to the argument that there is antecedent basis for the three-cup system, the Examiner does not agree and has added further explanation of this position in the objection. Applicant is referred to the objection of the claims and specification set forth earlier.

As with the claim objections, the Examiner has maintained the 35 USC 112, second paragraph rejections of claims 81-88 because of the open-ended ranges; see MPEP 2173.05(c)(II) which is incorporated here by reference.

In response to the argument pertaining to the Graham based obviousness rejections that the claimed ball diameter is not met, the Examiner has removed claim 1 from the rejected claims and has introduced a new reference to teach that the claimed dimensions were well known in the art. This was necessary because Applicants amended the remaining claims to introduce the new limitation pertaining to the ball diameter.

Applicants argued that there was no motivation to combine McKellop with Graham. In response, the Examiner asserts that the motivation is provided by McKellop in the abstract for crosslinking the polyethylene.

Next, Applicant argues that there are advantages for the claimed dimensions and that obvious design choice is not appropriate. In response, the Examiner, after

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reviewing the cited portions of the specification, concluded that the reasons are not pertinent to the claimed features in that they are either not drawn thereto or are too general in nature. For this reason, the rejections have not been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-

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2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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